SPECIFICATION

TITLE

"HEART STIMULATOR WITH STIMULATION CONTROLLED BY ANALYSIS OF AN AVERAGE IMPEDANCE MORPHOLOGY CURVE"

BACKGROUND OF THE INVENTION

Field of the Invention

The present invention relates to a heart stimulator for electric stimulation of a heart, of the type having comprising an impedance measuring unit that measures the impedance between at least two measurement electrodes implanted in a patient such that volume changes of at least one of the chambers of the left heart result in changes in the measured impedance, and an analyzer for analyzing the measured impedance for the control of the stimulation of the heart.

Description of the Prior Art

Heart stimulators of this above general type are known. United States Patent Nos. 5,334,422 and 5,584,868 and 6,223,079, disclose cardiac stimulating apparatus for use in heart failure therapy, wherein intracardiac impedance variations are used for sensing the cardiac function. United States Patent No. 4,535,774 discloses a rate responsive pacer which paces at a rate dependent on detected variations in the stroke volume of the heart. One mentioned example of inferring the stroke volume is by use of impedance measurements. For all these known devices the impedance sensing used for controlling the pacing is performed on beat-to-beat bases.

SUMMARY OF THE INVENTION

An object of the present invention is to provide an improved way of controlling the stimulation timing of a heart stimulator to optimize the patient hemodynamics.

The above object is achieved in accordance with the principles of the present invention in a heart stimulator of the type initially described, having a calculation unit

which calculates, for a predetermined stimulation pattern, an average impedance morphology curve during a time interval of several cardiac cycles, and an analyzer which analyzes the average impedance morphology curve for use for controlling the stimulation to optimize the patient's hemodynamics.

Thus in accordance with the present invention the measured left cardiac impedance averaged over several cardiac cycles is used for controlling the heart stimulation to optimize hemodynamics.

In an embodiment of the stimulator according to the invention the impedance measuring unit measures real and imaginary (in the mathematical sense) parts of impedance and the calculation unit calculates average values of the real and imaginary parts for use for the control of the stimulation. Blood is resistive and therefore, when the blood volume inside a left heart chamber increases the impedance phase angle will decrease. If, on the contrary, more heart tissue is present the impedance phase angle will become more negative. Therefore, the real and imaginary parts of the measured left cardiac impedance can be used in an advantageous way to optimize hemodynamics of the cardiovascular system. The impedance measuring unit has a measuring circuit preferably in the form of a synchronous demodulator, for obtaining both the real and imaginary parts of the impedance, and the impedance measuring unit can determine the impedance phase angle and the analyzer be adapted analyzes the phase angle for detecting and incipient CHF.

In another embodiment of the stimulator according to the invention the analyzer analyzes at least one predetermined parameter of the average impedance morphology curve for use for the control of the stimulation. A parameter having a value that is primarily dependent on the left ventricular ejection preferably is used.

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The parameter can be integrated area below the averaged impedance morphology curve versus time, maximum or minimum value of the average impedance morphology curve, the difference between maximum and minimum values of the average impedance morphology curve, the maximum positive or maximum negative slopes of the average impedance morphology curve, or the time between the maximum of the average impedance morphology curve and a predetermined beginning or end of the cardiac cycle.

In a further embodiment of the stimulator according to the invention wherein the stimulator is a multi-site stimulator, the control unit controls the stimulation-timing pattern. Once the optimal stimulation-timing pattern is established the stimulation is continuously adjusted to maintain the same pattern. A stimulation pattern can be considered as a vector of different time intervals and the control unit can first vary the VV-interval while keeping the AV-and AA-intervals constant until first optimum hemodynamics are obtained. The controlling unit then keeps the VV-interval at a constant value equal to the value giving optimum hemodynamics and also keeps the AA-interval constant while varying the AV-interval until second optimum hemodynamics are obtained. The control unit then keeps the AV-interval constant, equal to the AV-value giving the second optimum, and also keeps the VV-value at its above mentioned constant value while varying the AA-interval until third optimum hemodynamics are obtained. The control unit being then keeps the AA-interval constant equal to this AA-value giving the third optimum, and also keeps the AV-interval equal to its above mentioned constant AV-value while again varying the VV-interval until fourth optimum hemodynamics are obtained. The control unit continues this process until the optimums, obtained by the successive variation of these intervals, no longer are improved. It is beneficial to start this process by

successively sub-optimizing the VV-interval, the AV-interval and the AA-interval since changes in the VV-interval will affect the hemodynamics more than changes in the AV-interval, and changes in the AV-interval will affect hemodynamics more than changes in the AA-interval.

In this connection it should be noted that the VV timing for patients having Bundle Branch Block is essential for the well being of these patients. It has also been shown that resynchronization in patients having Left Bundle Branch Block improves there quality of life, e.g. improves the maximum oxygen consumption.

In another embodiment of the stimulator according to the invention the electrodes are designed for implantation in the right and left atria respectively or for implantation in the right atrium and left ventricle, the impedance thus measured being a measure of the blood volume of left atrium.

In another embodiment of the stimulator according to the invention the electrodes intended for the left atrium and the left ventricle are designed for implantation in a coronary vein.

DESCRIPTION OF THE DRAWINGS

Figure 1 is an example of a suitable electrode lead configuration for use in the heart stimulator according to the invention.

Figure 2 is a block diagram of an embodiment of a heart stimulator according to the present invention.

Figure 3 illustrates the impedance measured the across the left ventricle during four cardiac cycles with a first stimulation timing, followed by measurements during four cardiac cycles with a second stimulation timing.

Figure 4 shows averaged left ventricle impedance morphology curves determined for two different stimulation timings, and an ECG.

Figures 5, 6, 7, 8 and 9 respectively show different stimulation timing patterns as vectors representing different time intervals.

Figure 10 illustrates different quantities that can be derived in accordance with the invention from the measured left cardiac impedance.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Figure 1 illustrates suitable electrode configurations making impedance measurements possible at several places of the heart 2. By measuring the impedance between left atrium and right atrium RA electrode leads, or between left ventricle and right atrium leads, or possibly between a left atrium lead and the stimulator case, a signal corresponding to the left atrial blood filling is achieved to be used for hemodynamic optimization of the heart stimulator. A combination of signals obtained from these pairs of electrodes also can be used for this purpose. The left ventricular filling is suitably determined by measuring the impedance between an electrode implanted on the left ventricle and an electrode in the right ventricle. The electrodes intended for left atrium and left ventricle respectively are preferably designed for implantation in a coronary vein in CS. To get a good fixation of the electrode it is beneficial to use a screw-in electrode.

Excessive filling of blood in the left atrium and left ventricle can originate from several different cardiac dysfunctions. According to the invention this can be detected by impedance measurements, and the information obtained from this impedance measurement is used for controlling the stimulation such that hemodynamics are improved by improving the left heart-filling pattern.

Figure 2 is a block diagram of an embodiment of the heart stimulator according to the invention. A current i(t) is delivered from a current source 21 to electrodes 20, 22 and the evoked voltage response is measured between electrodes

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24, 26. The evoked voltage response is amplified in amplifier 28 and with the aid of a reference signal picked up from the current source 21 synchronized in a multiplier 30 with the current. A low pass filter 32 is used to obtain an average voltage signal $u_1(t)$. The corresponding average impedance curve Z_1 is given by

$$Z_1 = u_1/i$$

The average impedance morphology curve Z_1 obtained from a calculation unit 34 is analyzed in an analyzer 36. A control unit 38 is connected to the analyzer 36 to control the heart stimulation pulse generator 40 in response to the output from the analyzer 36 such that patient hemodynamics are optimized.

Figure 3 illustrates the impedance continuously measured across the left ventricle. The sampling frequency is high enough to make it possible to follow variations during each cardiac cycle, e.g. equal to 128 Hz. During the first four cardiac cycles shown in Figure 3 stimulation is performed according to a first stimulation-timing pattern Stim1, and during the four subsequent cardiac cycles the stimulation-timing pattern Stim2 is changed.

Figure 4 shows the average impedance morphology curve Z (Stim1) for a cardiac cycle, calculated during a time interval with a fixed stimulation-timing pattern Stim1. This time interval includes several cardiac cycles, e.g. 10-100 cycles. Thereafter one or more of the timing parameters are changed and a new average impedance morphology curve Z (Stim2) is calculated for a similar time interval. The ECG curve is also shown in Figure 4.

A quantity that is dependent on the left ventricular ejection is calculated from the average impedance morphology curves, Z cf. Figure 10 below. By comparing one of these quantities, e.g. the integrated area A, see Figure 10, for the two timings patterns Stim1 and Stim2 the most favorable of this two timing patterns is selected,

and this process can be continued for different stimulation timing patterns Stim such that the area A is maximized as an indication of a maximum stroke volume.

The stimulation timing pattern can be described as a vector of different time intervals (t_1, t_2, t_3), (t_1, t_2) etc., where t_1 is the time from right atrial T-wave detection to stimulation in the right ventricle, see Figures 5-7. The parameter t_1 can also be the time from a right atrial stimulation to right ventricular stimulation that should be selected independently from sensed events. Parameters t_2 and t_3 denote corresponding right atrium to left ventricle and right atrium to left atrium times respectively. Thus the parameters t_1, t_2 and t_3 define the AA-, AV- and VV-intervals, the parameters t_1 and t_2 and the quantity t_2–t_3 defining three different AV-intervals, as appears from Figure 5.

If it is not possible to stimulate or sense in the left atrium a three-chamber embodiment according to Figure 6 is selected. If the patient suffers from atrial fibrillation or atrial tachycardia only the two ventricles are involved in the optimization procedure, cf. Figure 9.

In Figure 7 the right AV-delay is optimized with reference to left ventricle blood filling. A coronary sinus lead is necessary to measure the left ventricle impedance.

Figure 8 illustrates a situation where a left ventricular lead is used only for measurement of the impedance Z.

Figure 10 shows eight examples of quantities, which can be derived from the measured left ventricular impedance. These quantities are integrated area A below the average impedance morphology curve Z versus time t, maximum and minimum values Z_{max} and Z_{min} of the average impedance morphology curve $\bar{Z}$ (diagrams B and C in Figure 10), the difference ΔZ between maximum and minimum values of the average impedance morphology curve $\bar{Z}$, (diagram D in Figure 10), the maximum

positive or maximum negative slopes dZ/dt of the average impedance morphology curve $\bar{Z}$ (diagrams E and F in Figure 10), and the time between the maximum Z_{max} of the average impedance morphology curve-Z and a predetermined beginning (QRS) or end of the cardiac cycle, (diagrams G and H in Figure 10). The maximum positive slope according to diagram E in Figure 10 represents maximum contraction velocity of the left ventricle and the maximum negative slope according to diagram F in Figure 10 represents the maximum relaxation velocity. The time t_c according to diagram G and the time t_r according to diagram H in Figure 10 represent the contraction and the relaxation times respectively of the left ventricle.

With the technique according to present invention a relatively stable optimum stimulation-timing pattern is obtained which only needs to be checked or verified at, preferably regular, intervals.

Besides the measured cardiac impedance's other quantities and conditions can also be considered for use in optimizing the stimulation-timing pattern. Thus e.g. rate and activity conditions as well as respiratory minute volume can be of importance in connection with optimization of the stimulation-timing pattern.

Although modifications and changes may be suggested by those skilled in the art, it is the intention of the inventors to embody within the patent warranted hereon all changes and modifications as reasonably and properly come within the scope of their contribution to the art.